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5 IN THE UNITED STATES DISTRICT COURT
6 FOR THE NORTHERN DISTRICT OF CALIFORNIA
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8 JEFFREY N WEISS,
9 Plaintiff,

10 v.

11 AMERICAN ACADEMY OF
12 OPHTHALMOLOGY, INC.,
13 Defendant.

Case No. [20-cv-08124-CRB](#)

**ORDER GRANTING MOTION TO
DISMISS**

14 Plaintiff Dr. Jeffrey Weiss is suing Defendant American Academy of
15 Ophthalmology, Inc. (AAO). Dr. Weiss alleges that AAO has been conducting an ethics
16 investigation of Dr. Weiss without following AAO's bylaws. AAO's Ethics Committee
17 has recommended that Dr. Weiss be suspended for three years and banned from engaging
18 in various activities, though AAO's Board of Trustees has not taken final action.

19 The Court granted AAO's motion to dismiss Dr. Weiss's original complaint with
20 leave to amend. Based on harm that Dr. Weiss might suffer if the Board of Trustees
21 suspends or otherwise disciplines him, and harm that Dr. Weiss states that his practice has
22 already suffered as a result of the investigation, Dr. Weiss's amended complaint asserts
23 claims for breach of contract, violations of the Florida Deceptive and Unfair Trade Practice
24 Act and California Business and Professions Code section 17200, and declaratory relief.
25 AAO has moved to dismiss the amended complaint for lack of subject matter jurisdiction
26 and failure to state a claim for which relief may be granted. The Court concludes that oral
27 argument is unnecessary. The Court grants AAO's motion to dismiss but again gives Dr.
28 Weiss leave to amend.

I. BACKGROUND

A. Facts

Dr. Weiss, a Florida resident, is an ophthalmologist and AAO member. See Amend. Compl. (dkt. 36) ¶ 3. In 2013 and 2015, Dr. Weiss designed two studies “involving the isolation of autologous bone marrow derived stem cells . . . and the transfer of those cells to the eyes” of visually impaired patients. Id. ¶ 22. Both studies were annually reviewed and approved by the International Cellular Medical Society’s Institutional Review Board (IRB). Id. ¶ 23.

AAO’s “Code of Ethics” includes “Rules of Ethics” and “Administrative Procedures.” Id. ¶ 10.¹ The Rules of Ethics are “mandatory” and “enforceable.” Id. ¶ 12. The version of Rule 3 that is relevant here—i.e., the version in place before Rule 3 was amended in 2020—stated:

Research and innovation shall be approved by appropriate review mechanisms to protect patients from being subjected to or potentially affected by inappropriate, ill-considered, or fraudulent basic science or patient-oriented research. Basic science and clinical research are conducted to develop adequate information on which to base prognostic or therapeutic decisions or to determine etiology or pathogenesis, in circumstances in which insufficient information exists. Appropriate informed consent for research and innovative procedures must recognize their special nature and ramifications. In emerging areas of ophthalmic treatment where recognized guidelines do not exist, the ophthalmologist should exercise careful judgment and take appropriate precautions to safeguard patient welfare.

Amend. Compl. ¶ 13.² At all times relevant here, Rule 13 has stated:

¹ The Code of Ethics also includes aspirational “Principles of Ethics.” Amend. Compl. ¶¶ 10–11. The Court considers the Code of Ethics when ruling on this motion because the amended complaint incorporates the Code of Ethics by reference. See Khoja v. Orexigen Therapeutics, Inc., 899 F.3d 988, 998 (9th Cir. 2018).

² In January 2020, Rule 3 was amended as follows:

Research is conducted to provide information on which to base diagnostic, prognostic or therapeutic decisions and/or to improve understanding of pathogenesis in circumstances in which sufficient information exists. Research and innovation must be approved by appropriate review mechanisms (Institutional Review Board: IRB) and must comply with all requirements of the approved study protocol to protect patients from being subjected to or potentially affected by inappropriate or fraudulent research. In emerging areas of

Communications to the public must be accurate. They must not convey false, untrue, deceptive, or misleading information through statements, testimonials, photographs, graphics or other means. They must not omit material information without which the communications would be deceptive. Communications must not appeal to an individual's anxiety in an excessive or unfair way; and they must not create unjustified expectations of results. If communications refer to benefits or other attributes of ophthalmic procedures that involve significant risks, realistic assessments of their safety and efficacy must also be included, as well as the availability of alternatives and, where necessary to avoid deception, descriptions and/or assessments of the benefits or other attributes of those alternatives. Communications must not misrepresent an ophthalmologist's credentials, training, experience, or ability, and must not contain material claims of superiority that cannot be substantiated. If a communication results from payment by an ophthalmologist, this must be disclosed unless the nature, format or medium makes it apparent.

Amend. Compl. ¶ 16.

Under the Administrative Procedures, an Ethics Committee has authority to investigate whether an AAO member has violated the Rules of Ethics. Id. ¶ 18. The Code of Ethics provides detailed procedures for investigations that result in ethics challenges. See Code of Ethics (dkt. 36-2) § (C)(4). Such investigations "are conducted in confidence," and the Ethics Committee must give written notice of "the factual details of the challenge with sufficient particularity to permit the . . . member to respond to the challenge and prepare any necessary defense." Amend. Compl. ¶¶ 19, 41; Code of Ethics § (C)(2)(c).

Although the Ethics Committee has authority to submit a recommendation to AAO's Board of Trustees, the Board of Trustees is responsible for making a final

ophthalmic treatment where recognized guidelines do not exist, the ophthalmologist should exercise careful judgment and take appropriate precautions to safeguard patient welfare. Appropriate informed consent for research and innovative procedures must recognize their special nature and ramifications. The ophthalmologist must demonstrate an understanding of the purpose and goals of the research and recognize and disclose financial and non-financial conflicts of interest. Commensurate with the level of his/her involvement, the investigator [performing the research] must accept personal accountability for patient safety and compliance with all legal and IRB-imposed requirements.

Amend. Compl. ¶ 15. Rule changes do not apply retroactively. See id. ¶ 19; Code of Ethics (dkt. 36-2) § (C)(1)(d).

determination that there has been a breach and for imposing appropriate sanctions.

See Code of Ethics §§ (C)(4)(b)–(c).

Dr. Weiss alleges that on July 24, 2017, the Ethics Committee informed Dr. Weiss that it was concerned about his autologous bone marrow derived stem cell studies (particularly with respect to “patient selection, patient fees, and reported results”) and asked Dr. Weiss to answer ten questions about them. See id. ¶ 26. After Dr. Weiss responded with answers, on December 19, 2017, the Ethics Committee informed Dr. Weiss that it wished to review his research to assess his compliance with the AAO’s Rules of Ethics, including Rule 3. Id. ¶¶ 27–28. The Ethics Committee raised additional concerns regarding whether Dr. Weiss’s studies had “well-designed protocols,” along with issues relating to “postoperative care and the medical procedure involved in the studies.” Id. ¶¶ 28–29. “The [Ethics] Committee also questioned patient-funded research in general and . . . noncommercial publications discussing Dr. Weiss’s research.” Id. ¶ 29.

Dr. Weiss requested that the Ethics Committee provide him with more details about the ethics challenge such that he could respond and prepare a defense. Id. ¶ 30. He alleges that the Ethics Committee did not provide that information. Id. ¶ 31. On March 16, 2018, Dr. Weiss reiterated to the Ethics Committee that his studies were IRB approved. Id.

On May 1, 2018, the Committee “began a formal challenge into Dr. Weiss’s compliance with the Code of Ethics.” Id. ¶ 32.³ The Committee expressed concerns about “research protocols,” the “scientific basis for the studies,” “participation fees,” and “advertisement” of the studies. Id. The Committee also requested “objective documentation” of the results of the studies, plus a “dataset and analysis with corresponding calculations.” Id. ¶¶ 32, 34. In response, Dr. Weiss produced more than 40,000 pages containing “the charts for the study participants,” comprising his “raw patient data,” but explained that he had never prepared a “dataset and analysis” of the type

³ Dr. Weiss alleges that the Committee did not disclose the factual basis of the ethics challenge when asked to do so before May 2018, but also alleges that a formal challenge began on May 1, 2018. This apparent discrepancy is not material to the Court’s analysis.

1 requested because “he never had an obligation to do so.” Id. ¶¶ 33–34.

2 On November 21, 2020, the Ethics Committee held a virtual hearing “to address Dr.
3 Weiss’s alleged non-observance of Rules of Ethics 3 and 13.” Id. ¶ 36. According to Dr.
4 Weiss, the Committee alleged that Dr. Weiss’s data did not “substantiate the publicly made
5 claims for safety and efficacy of the research nor [did] it indicate compliance with aspects
6 of the version of Rule 3 in effect when this investigation began.” Id. ¶ 36. Dr. Weiss
7 alleges that the Committee asserted that Dr. Weiss breached Rule 13 because Dr. Weiss’s
8 data did not “substantiate the claims he made in medical journals and publications.” Id.

9 On February 18, 2021, the Ethics Committee recommended that the AAO Board of
10 Trustees “impose on Dr. Weiss [a] 3-year membership suspension with a concurrent ban
11 on sponsoring, presenting or participating in a lecture, poster, film, instruction course,
12 panel or exhibit booth at any meeting or program offered by or sponsored by the academy
13 based on alleged non-observance of Rule 3 and 13.” Id. ¶ 38. Dr. Weiss does not allege
14 that the Board of Trustees has accepted this recommendation or otherwise taken final
15 action against Dr. Weiss. Dr. Weiss does allege that his medical practice is “heavily
16 dependent on patient referrals,” that the Ethics Committee has “ignored” the
17 Administrative Procedure requiring that investigations be conducted in confidence, and
18 that, “as a consequence, Dr. Weiss’s practice has been mortally damaged.” Id. ¶ 41 (citing
19 Code of Ethics § (C)(2)(c)).

20 **B. Procedural History**

21 On November 18, 2020—before the Ethics Committee made any recommendation
22 to the Board of Trustees—Dr. Weiss sued AAO, alleging that AAO was violating Dr.
23 Weiss’s “right of fair procedure” under California law. See Complaint (dkt. 1) at 11. On
24 December 11, 2020, Dr. Weiss moved for a preliminary injunction. See Mot. for
25 Injunction (dkt. 14). AAO moved to dismiss. See Mot. to Dismiss (dkt. 17).

26 On January 15, 2021, the Court denied Dr. Weiss’s motion for a preliminary
27 injunction and granted AAO’s motion to dismiss. See Order Granting MTD (dkt. 33) at 6–
28 7. The Court concluded that it lacked jurisdiction over Dr. Weiss’s “right of fair

procedure” claim because such a claim must allege the termination of some benefit. Dr. Weiss had not suffered a cognizable injury and thus lacked standing to assert the claim. Id. at 7. To the extent that Dr. Weiss had alleged a concrete injury based on financial harm to his practice, Dr. Weiss had not asserted any additional cause of action based on that harm and had thus failed to state a claim for which relief may be granted. Id. at 8. The Court gave Dr. Weiss leave to amend. Id.

On February 22, 2021, Dr. Weiss filed the amended complaint at issue here. The amended complaint includes allegations relating to the Ethics Committee’s recommendation that the Board of Trustees sanction Dr. Weiss. Amend. Compl. ¶ 38. Dr. Weiss no longer asserts a “right to fair procedure” claim, but asserts claims for breach of contract and violations of the Florida Deceptive and Unfair Trade Practice Act and California Business and Professions Code section 17200. Id. ¶¶ 44–68. Dr. Weiss requests declaratory relief, an injunction, damages, restitution, and attorneys’ fees. Id. at 15–17. AAO has moved to dismiss for lack of subject matter jurisdiction and failure to state a claim for which relief may be granted. See Mot. to Dismiss FAC (dkt. 40).

II. LEGAL STANDARD

A. Jurisdiction

Under Article III of the U.S. Constitution, the Court has jurisdiction over only “cases” and “controversies.” U.S. Const. Art. III. There is no Article III case or controversy if a plaintiff lacks standing. See, e.g., Spokeo, Inc. v. Robins, 136 S. Ct. 1540, 1547 (2016). To have standing, a plaintiff must establish (1) that he has suffered an injury in fact, (2) that his injury is fairly traceable to a defendant’s conduct, and (3) that his injury would likely be redressed by a favorable decision. See Lujan v. Defenders of Wildlife, 504 U.S. 555, 560–61 (1992). To establish an injury in fact, the plaintiff must demonstrate “‘an invasion of a legally protected interest’ that is ‘concrete and particularized’ and ‘actual or imminent, not conjectural or hypothetical.’” Spokeo, 136 S. Ct. at 1548 (quoting Lujan, 504 U.S. at 560).

“[R]ipeness doctrine is drawn both from Article III limitations on judicial power

and from prudential reasons for refusing to exercise jurisdiction.” Nat’l Park Hospitality Ass’n v. Dep’t of Interior, 538 U.S. 803, 808 (2003) (citation omitted). Ripeness is “designed to separate matters that are premature for review because the injury is speculative and may never occur from those cases that are appropriate for federal court action.” Wolfson v. Brammer, 616 F.3d 1045, 1057 (9th Cir. 2010) (citation omitted). “Ripeness has both constitutional and prudential components.” Id. The constitutional component “overlaps” with Article III’s “injury in fact” analysis, and requires determining “whether the issues presented are definite and concrete, not hypothetical or abstract.” Id. (citation omitted). The prudential component requires considering “the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.” Id. (quoting Abbot Labs v. Gardner, 387 U.S. 136, 149 (1967)).

A request for a declaratory judgment necessarily implicates these Article III considerations. The Declaratory Judgment Act gives federal courts discretion to “declare the rights and other legal relations of any interested party seeking such declaration,” but only “[i]n a case of actual controversy within its jurisdiction.” 28 U.S.C. § 2201(a). Thus, in determining whether it should issue a declaratory judgment, a court “must first inquire whether there is an actual case or controversy within its jurisdiction.” Principal Life Ins. Co. v. Robinson, 394 F.3d 665, 669 (9th Cir. 2009). If there is, the Court must then “decide whether to exercise its jurisdiction.” Id. At the first step, the case or controversy requirement is “identical to Article III’s case or controversy requirement.” Id. (quoting American States Ins. Co. v. Kearns, 15 F.3d 142, 143 (9th Cir. 1994)). “If a case is not ripe for review, then there is no case or controversy, and the court lacks subject matter jurisdiction.” Id. The question is whether “there is a substantial controversy, between parties having adverse legal interest, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” Id. at 671 (quoting Maryland Cas. Co. v. Pacific Coal & Oil Co., 312 U.S. 270, 273 (1941)). At the second step, in determining whether to exercise its jurisdiction to issue a declaratory judgment, the district court “must balance concerns of judicial administration, comity, and fairness to litigants.” Id. at 672

(citation omitted).

B. Motion to Dismiss

Under Rule 12(b)(6) of the Federal Rules of Civil Procedure, a complaint may be dismissed for failure to state a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(6). Rule 12(b)(6) applies when a complaint lacks either “a cognizable legal theory” or “sufficient facts alleged” under such a theory. Godecke v. Kinetic Concepts, Inc., 937 F.3d 1201, 1208 (9th Cir. 2019). Whether a complaint contains sufficient factual allegations depends on whether it pleads enough facts to “state a claim to relief that is plausible on its face.” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citing Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A claim is plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” Id. at 678. Evaluating a motion to dismiss, the Court “must presume all factual allegations of the complaint to be true and draw all reasonable inferences in favor of the nonmoving party.” Usher v. City of Los Angeles, 828 F.2d 556, 561 (9th Cir. 1987). “[C]ourts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice.” Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007).

If a court dismisses a complaint for failure to state a claim, it should “freely give leave” to amend “when justice so requires.” Fed. R. Civ. P. 15(a)(2). A court has discretion to deny leave to amend due to “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendment previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [and] futility of amendment.” Leadsinger, Inc. v. BMG Music Pub., 512 F.3d 522, 532 (9th Cir. 2008).

III. DISCUSSION

Here again, Dr. Weiss has not stated a claim for relief. To the extent that Dr.

Weiss's claims arise from the injuries he may suffer if finally sanctioned by the AAO Board of Trustees, Dr. Weiss has suffered no concrete injury. Dr. Weiss has alleged a concrete injury with respect to the harm that his medical practice has already suffered as a result of the investigation. But he has not stated a claim for which relief may be granted based on that harm because his relevant allegations are not detailed enough to plausibly demonstrate that AAO has breached any provision in the Code of Ethics.

A. Jurisdiction

Dr. Weiss has not suffered a concrete injury based on the sanctions that the Ethics Committee has recommended to the Board of Trustees. Whether Dr. Weiss will be sanctioned is up to the Board of Trustees, which has not yet acted. Dr. Weiss has not plausibly alleged that the Board of Trustees imposes recommended sanctions as a matter of course. Thus, any harm that Dr. Weiss may suffer at the conclusion of the inquiry is "hypothetical" and "abstract." Wolfson, 616 F.3d at 1057. And, as before, Dr. Weiss's request for a declaratory judgment does not change this conclusion. Because Dr. Weiss's potential future injury fails to satisfy the requirements of standing and ripeness, it does not give rise to an Article III case or controversy and does not fall within the Court's jurisdiction under the Declaratory Judgment Act. See Principal Life Ins. Co., 394 F.3d at 669.

Dr. Weiss's other allegations establish a past concrete injury. Dr. Weiss alleges that his medical practice has already suffered financially due to disclosure of the investigation. See Amend. Compl. ¶ 41. In that sense, Dr. Weiss alleges that he has suffered a financial injury, caused by AAO, which could be remedied by a favorable judicial decision. See Lujan, 504 U.S. at 560–61. Thus, Dr. Weiss has standing to assert claims relating to the injury caused by disclosure of the ethics inquiry.

B. Rule 12(b)(6)

That said, Dr. Weiss's allegations of financial harm are not particularized enough to state a claim for which relief may be granted.

Dr. Weiss has not plausibly stated a breach of contract claim relating to disclosure

of the ethics inquiry.⁴ According to Dr. Weiss, his practice suffered because AAO “ignored” Code of Ethics § (C)(2)(c)’s confidentiality requirement. Like AAO, the Court assumes that AAO’s failure to adhere to a Code of Ethics provision could constitute a breach of contract. See Mot. to Dismiss at 2 n.2.⁵ Nonetheless, Dr. Weiss has not plausibly stated a breach of contract claim based on the confidentiality provision. By simply stating that AAO ignored the confidentiality rule and thus harmed Dr. Weiss’s practice, Dr. Weiss has omitted any information regarding who at AAO ignored the rule, what was disclosed, when the prohibited disclosure occurred, how disclosure impacted patient referrals, or any other details. Therefore, the amended complaint does not plead enough details to “state a claim to relief that is plausible on its face.” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). The Court gives Dr. Weiss leave to amend so that he may provide those additional details.

The Court also notes that even if Dr. Weiss’s allegations established some other concrete injury based on the ethics investigation more generally, Dr. Weiss has not plausibly alleged that AAO breached other contractual provisions. Dr. Weiss argues that AAO breached the Code of Ethics by asserting that Dr. Weiss violated (i) Rule 3, despite his studies having IRB approval, and (ii) Rule 13, although that rule does not apply to his noncommercial speech. See Opp. (dkt. 48) at 9. But the Rules show that these arguments are meritless. IRB approval would not foreclose an investigation under the operative version of Rule 3. In addition to requiring “appropriate review mechanisms,” Rule 3 unambiguously required ophthalmologists to provide study participants with certain information and to “exercise careful judgment and take appropriate precautions to safeguard patient welfare” when performing research in “emerging areas . . . where recognized guidelines do not exist.” Amend. Compl. ¶ 13.⁶ Thus, an IRB-approved study

⁴ The Court need not decide which state’s law applies to Dr. Weiss’s breach of contract claim, because the Court’s reasoning is based on generally applicable contract principles that do not vary across states.

⁵ The Court notes that AAO has preserved arguments to the contrary. See Mot. to Dismiss at 2 n.2.

⁶ Contrary to Dr. Weiss, see Opp. at 9, Rule 3 did not state or imply that a study approved by an

could still violate Rule 3. Similarly, Rule 13 applies to all “[c]ommunications to the public,” such that even noncommercial communications could violate Rule 13. Id. ¶ 16.⁷ Furthermore, even if there were some doubt about Rule 3 and Rule 13’s language, AAO does not breach any provision in the Code of Ethics when its Ethics Committee merely investigates a possible violation of the Rules. Assuming that the Code of Ethics is a contract, Dr. Weiss has contracted to give the Board of Trustees, on recommendations from the Ethics Committee, authority to interpret and enforce those Rules.

In sum, other than the confidentiality provision discussed above, Dr. Weiss has not identified any provision of the Code of Ethics that AAO has breached. And with respect to that confidentiality provision, Dr. Weiss has not provided enough detail.

For the same reasons, Dr. Weiss has failed to plausibly state Florida Unfair and Deceptive Trade Practices Act and California Business and Professions Code section 17200 claims. These claims are premised on Dr. Weiss’s assertion that AAO has breached the Code of Ethics. See Amend. Compl. ¶¶ 56, 65(b). Even if Dr. Weiss alleged a concrete injury—which he has not except with respect to financial harm to his medical practice—Dr. Weiss has not plausibly alleged such a breach.

IV. CONCLUSION

For the foregoing reasons, the Court grants AAO’s motion to dismiss the amended complaint. The Court grants Dr. Weiss leave to amend his complaint once again. See Leadsinger, 512 F.3d at 532. Dr. Weiss may file a second amended complaint within 30 days from the date of this order.

IT IS SO ORDERED.

Dated: May 14, 2021



CHARLES R. BREYER
United States District Judge

IRB or other appropriate review mechanism is necessarily excluded from the category of studies in emerging areas where recognized guidelines do not exist.

⁷ Dr. Weiss argues that the speech at issue is constitutionally protected, see Opp. at 13, but does not adequately explain why that is significant here, where Dr. Weiss apparently contracted with a private entity to not engage in certain speech.